REMARKS

Claims 1-18 are pending in the application. Claims 1-18 stand rejected under 35 U.S.C. 102(b) as being anticipated by Snyders (U.S. Publication No. 2002/0123802 A1). Applicant notes that Snyders also issued as U.S. Patent No. 6,821,297. Applicant requests reconsideration.

Claim 1 sets forth a cuff for medical use wherein the cuff is made of a flexible openwork structure of a medically acceptable metal. Claim 1 is supported at least by page 1, lines 9-11, page 2, line 36 to page 3, line 10, and elsewhere throughout the present specification. Page 2 of the Office Action alleges that Snyders discloses each and every limitation of claim 1. However, Applicant asserts that Snyders fails to disclose, or even suggest, every limitation of claim 1.

Page 2 of the Office Action refers to paragraph 56 and Fig. 8 of Snyders, describing outer portion 260 containing Nitinol(R) or other metals, as allegedly disclosing the subject matter of claim 1. However, the referenced text fails to disclosed or suggest a cuff. Review of the remainder of Synders fails to reveal disclosure or suggestion of the claimed cuff.

Specifically, paragraph 42 of Snyders discusses a band 40 shown in Fig. 2 for an artificial valve 10M. Band 40 is not disclosed as including a medically acceptable metal. In fact, paragraph 42 describes band 40 as having the same conventional structure as discussed in the "Background Art" section of the present application. Snyders describes using Dacron(R) or other fabric "to provide sites for vascular connective tissue ingrowth to enhance the stability of the device after its implantation." Snyders fails to

recognize the advantage of using a medically acceptable metal as an exterior surface of band 40. At least for such reasons, Snyders fails to disclose or suggest every limitation of claim 1.

Paragraph 42 of Snyders also describes a rim or flange (not shown) surrounding the valve for engaging cusps of heart H shown in Fig. 1. Even so, Snyders fails to disclose or suggest such a rim or a flange including a medically acceptable metal. At least for such additional reasons, Snyders fails to disclose or suggest every limitation of claim 1.

Since the Office Action previously referred to outer portion 260 of artificial valve 210 as disclosing the claimed cuff, Applicant notes that Snyders fails to support modification of outer portion 260 in a manner such that it would disclose the claimed cuff. That is, a cuff for medical use dimensioned for sewing in place in the body as discussed on page 1, lines 9-11 and page 2, line 36 to page 3, line 10 of the present specification. Specifically, paragraph 55 of Snyders states that the purpose of outer portion 260 includes preventing "the inner portion 258 from protruding outward beyond the frame elements 230 when the artificial valve 210 is collapsed." Thus, outer portion 260 prevents inner portion 258 "from prolapsing outwardly as the valve collapses, which could impede loading of the artificial valve 210 into a holder 276." Since a prolapsed inner portion 258 protruding beyond frame elements 230 could impede loading, those of ordinary skill would appreciate that a cuff dimensioned for sewing in place in the body could also impede loading. Accordingly, modification of artificial valve 210 to include the claim 1 cuff is inappropriate.

The motivation for modifying a reference must be something other than hindsight reconstruction based on using Applicants' invention as a road map for such combination. See, e.g., Interconnect Planning Corp. v. Veil, 227 USPQ 543, 551 (Fed. Cir. 1985); In re Mills, 16 USPQ2d 1430 (Fed. Cir. 1990) (explaining that hindsight reconstruction is an improper basis for rejection of a claim). Also, the mere fact that the prior art can be modified does not make the modification obvious "unless the prior art suggested the desirability of the modification." In re Gordon, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984). Accordingly, if a proposed modification of the prior art would render the prior art device or process "inoperable for its intended purpose" or change the principle of operation of the prior art invention being modified, then no suggestion or motivation exists to make the proposed modification. Id.; In re Ratti, 270 F.2d 810, 123 USPQ 349 (CCPA 1959); MPEP § 2143.01. Applicant asserts that Snyders expressly states that modification of artificial valve 210 to disclose the claim 1 cuff could frustrate the intended purpose of Snyders. At least for such further reason, Snyders fails to disclose or suggest every limitation of claim 1.

Applicant acknowledges that judgments on obviousness may necessarily involve a reconstruction based in a sense on hindsight reasoning. However, such reconstruction can only take into account knowledge that was within the level of ordinary skill in the art at the time the claimed invention was made and cannot include knowledge gleaned only from Applicant's disclosure. In re McLaughlin, 443 F.2d 1392, 1395, 170 USPQ 209, 212 (CCPA 1971); MPEP 2145(X)(A). Snyders fails to disclose or suggest the

advantages associated with a cuff using a medically acceptable metal, as claimed. Only the Applicant's own specification discloses such structures and their benefits. At least for such still further reason, claim 1 is patentable over Snyders.

Claims 2, 4, 5, 11, and 13 depend from claim 1 and are not anticipated by Snyders at least for such reason as well as for the additional limitations of such claims not disclosed or suggested. For example, claim 2 sets forth that the cuff is formed to provide a cuff for a heart valve, a cuff for a line, a barrier cuff for a peritoneal dialysis catheter, an annuloplasty band, or an annuloplasty ring. Snyders fails to disclose or suggest the claimed cuff formed to provide such structures.

Claim 3 sets forth a cuff for a mechanical heart valve, wherein the cuff includes a flexible openwork structure of a medically acceptable wire and provides an inner annular rim dimensioned to fit around the perimeter of the heart valve and formed integrally with an outer annulus of larger diameter than the inner annular rim. As set forth at least on page 2, line 36 to page 3, line 17 of the present specification, the claim 3 cuff has the advantage of including structures that allow it to be sewn into place and/or to provide other advantages related to promoting good tissue growth. Page 2 of the Office Action alleges that Snyders discloses each and every limitation of claim 3. Applicant asserts that Snyders fails to disclose or suggest every limitation of claim 3.

The Office Action alleges that Snyders discloses a woven mesh cuff inherently providing an outer annular portion with a larger diameter than the

inner annular rim, such as in claim 8. However, Applicant asserts that the relied upon portion of Snyders and elsewhere throughout Snyders fails to disclose or suggest the claimed cuff, such as shown in Figs. 1-2 of the present specification. At least for such reason, Snyders fails to disclose each and every limitation of claim 3. Further, as may be appreciated from the discussion above regarding the deficiencies of Snyders as applied to claim 1, modification of Snyders to provide the claim 3 cuff is inappropriate.

Claims 12 and 14 depend from claim 3 and are not anticipated at least for such reason as well as for the additional limitations of such claims not disclosed or suggested.

Claim 6 sets forth a method of promoting tissue ingrowth and endothelialisation and minimising the risk of foreign body infection following the insertion of a cuff in the living subject. The method includes, among other features, providing a cuff made of a medically acceptable metal. As may be appreciated from the discussion above regarding the deficiencies of Snyders as applied to claims 1-3, Snyders fails to disclose each and every limitation of claim 6. Thus, Snyders does not anticipate claim 6. Claims 9 and 10 depend from claim 6 and are not anticipated at least for such reason as well as for the additional limitations of such claims not disclosed.

Claim 7 sets forth a method of promoting tissue ingrowth and endothelialisation, minimising the risk of a foreign body infection and minimising paravalvular leaks following the fitting of a prosthetic heart valve mounted upon a cuff. The method includes, among other features, providing a prosthetic heart valve having a peripheral cuff made of a medically

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acceptable metal. As may be appreciated from the discussion above regarding the deficiencies of Snyders as applied to claims 1-3, Snyders fails to disclose each and every limitation of claim 7. Thus, Snyders does not anticipate claim 7. Claims 8 and 15-18 depend from claim 7 and are not anticipated at least for such reason as well as for the additional limitations of such claims not disclosed or suggested.

At least for the reasons indicated above, Snyders does not anticipate claims 1-18 and Applicant requests allowance of such claims in the next Office Action.

Applicant herein establishes adequate reasons supporting patentability of claims 1-18 and requests allowance of all pending claims in the next Office Action.

Respectfully submitted,

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